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Practitioner's Docket No. 30394-1027

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

Inventor(s)

for

Title of invention

OR

MAR 24 2000

In re application of: Waltherus J.W. van Venrooij

TECH CENTER 1600/2900

Application No.: 0 9/ 308,150

Group Art Unit: 1614

Filed: September 30, 1999

Examiner:

For: PEPTIDE DERIVED FROM AN ANTIGEN RECOGNIZED BY ANTIBODIES...

Assistant Commissioner for Patents
Washington, D.C. 20231

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT
WITHIN THREE MONTHS OF FILING OR
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in § 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. § 1.97(b).

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. § 1.8(a))

I hereby certify that this correspondence is, on the date shown below, being:

MAILING

☒ deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: March 17, 2000

FACSIMILE

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

DEBORAH A. PEACOCK

(type or print name of person certifying)

(Transmittal of Information Disclosure Statement Within Three Months of Filing or Before Mailing of First Office Action [8-3]—page 1 of 2)

MAR 24 2000

TECH CENTER 1600/2900

NOTE: The "filing date of a national application" under 37 C.F.R. § 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 C.F.R. § 1.53(b) as "the date on which: (1) A specification containing a description pursuant to § 1.71 and at least one claim pursuant to § 1.75; and (2) any drawing required by § 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by § 1.41." 37 C.F.R. § 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. § 371(c) within the periods set forth in § 1.494 or § 1.495. 35 U.S.C. § 371(c) requires the filing of the following: (1) the basic national fee; (2) a copy of the international application, unless already sent by the International Bureau, and optionally an English translation if filed in another language; and, also optionally (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. The optional items must be submitted later, with surcharges. 37 C.F.R. § 1.97(b)(2).

IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION DISCLOSURE STATEMENT

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

NOTE: "No certification or fee is due when the filing is made within the above time period. It is advisable to ensure that no Office action has been mailed if the disclosure statement is delayed until after three months from filing."

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 C.F.R. 1.8, or Express Mail certificate under 37 C.F.R. 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 C.F.R. 1.142) or just a requirement for additional fees to have a claim considered (37 C.F.R. 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. § 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).


SIGNATURE OF PRACTITIONER
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Practitioner's Docket No. 30394-1027

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Waltherus J.W. van Venrooij, et al

Serial No. 09/308,150

Filing date: September 30, 1999

Examiner: UNKNOWN

For: PEPTIDE DERIVED FROM AN ANTIGEN
RECOGNIZED AS AUTOANTIBODIES
FROM PATIENTS WITH RHEUMATOID
ARTHRITIS, ANTIBODY DIRECTED AGAINST
SAID PEPTIDE, A COMBINATORIAL ANTIGEN
AND A METHOD OF DETECTING AUTO-
IMMUNE ANTIBODIES

Group: 1614

Assistant Commissioner for Patents
Washington, D.C. 20231

FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

CERTIFICATION UNDER 37 C.F.R. 1.8(a) AND 1.10

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

☒ deposited with the United States Postal Service on the date shown below in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

☒ under 37 CFR 1.8(a) with sufficient postage as first class mail;

☐ under 37 CFR 1.10 as "Express Mail Post Office to Addressee", **Mailing Label No. EL US** (mandatory);

TRANSMISSION

☐ transmitted by facsimile to the Patent and Trademark Office.

Date: March 17, 2000

DEBORAH A. PEACOCK

(Type or print name of person mailing paper)

(Signature of person mailing paper)

WARNING: Each paper or fee filed by Express Mail **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).

"Since the filing of correspondence under 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439 at 56,442.

Note: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) within three months of the date of entry of the national stage as set forth in ' 1.491 in an international application; or
- (3) Before the mailing of a first Office Action on the merits, whichever event occurs last." 37 C.F.R. 1.97(b).

Note: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 CFR 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 CFR 1.56(c).

Note: The "duty as described in § 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by " 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 CFR § 1.51(b).

LIST OF SECTIONS FORMING PART OF THIS INFORMATION DISCLOSURE STATEMENT

(check sections forming a part of this statement; discard unused sections and number pages consecutively)

The following sections are being submitted for this Information Disclosure Statement:

1. X Preliminary Statements
2. X Forms PTO/SB/08A and 08B (formerly PTO-1449)
3. Statement as to Information Not Found in Patents or Publications
4. Identification of Prior Application in which Listed Information was Already Cited and For
Which No Copies are Submitted or Need be Submitted.
5. Cumulative Patents or Publications
6. X Copies of Listed Information Items Accompanying This Statement
7. Concise Explanation of Non-English Language Listed Information Items
 7A. EPO Search Report
 7B. English Language Version of EPO Search Report
8. Translation(s) of Non-English Language Documents
9. Concise Explanation of English Language Listed Information Items (Optional)
10. X Identification of Person(s) Making This Information Disclosure Statement

Sections _____, respectively have been continued on ADDED PAGE(S).
("Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37))

Section 1. Preliminary Statements

Applicant(s) submit herewith patents, publications or other information of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR 1.97(g)) an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G., 13-25, at 25.

Section 2. Form PTO-1449 (Modified) (PTO/SB/08A and 08B.

A list of the patent(s) and/or publication(s) is set forth on the attached one (1) page(s) of Form PTO-1449 (Modified). (Form(s) PTO-1449 attached at the end of this paper)

NOTE: With respect to the list required by paragraph (b) of 37 CFR 1.98, the Notice of April 20, 1992 (1138 O.G. 37-41) points out that:
"The list may not be incorporated into the specification but must be submitted in a separate paper. A separate list is required so that it is easy to confirm that applicant intends to submit an information disclosure statement, and because it provides a readily available checklist for the examiner to indicate which identified documents have been considered. A copy of a separate list will also provide a simple means of communication to applicant to indicate the listed documents that have been considered and those listed documents that have not been considered. Use of Form PTO-1449, "Information Disclosure Citation, is encouraged."

NOTE: "An information disclosure statement may include two lists (and two certifications)...in situations where some of the information listed was cited in a communication from a foreign patent office not more than three months prior to filing the statement and some was not, but was not known more than three months prior to the filing the statement." Notice of April 20, 1992 (1138 O.G. 37-41, 40).

NOTE: With respect to the examiner's consideration of the Information Disclosure Statement, the Notice of April 20, 1992 (1138 O.G. 37-41) states:

"If information is listed in the specification rather than in a separate paper, or if the other content requirements ***are not complied with, the examiner will notify applicant in the next Office action that the information has not been considered. It should be noted, however, that no copy of a U.S. patent application is required to be submitted. *** Where a U.S. patent application is properly cited, the examiner should obtain access to that file within the Office.

"Examiners must consider all citations submitted in conformance with the rules and this section and place their initials adjacent the citations on a list or in the boxes provided on a form PTO-1449. If the citations are submitted on a list other than a form PTO-1449, the examiner may write "all considered" and his or her initials to indicate that all citations have been considered. If any of the citations are considered, a copy of the submitted list or form, as reviewed by the examiner, will be returned to the applicant with the next communication. The original copy of the form will be entered into the application file. The copy returned to the applicant will serve both as acknowledgment of receipt of the information disclosure statement and as an indication that the references were considered by the examiner. Forms PTO-326 and PTOL-37 include a box to indicate the attachment of form PTO-1449.

"Information which complies with requirements as discussed in this section but which is in a non-English language will be considered in view of the concise explanation submitted *** and insofar as it is understood on its face, e.g., drawings, chemical formulas, in the same manner that non-English language information in Office search files is considered by examiners in conducting searches. The examiner need not have the information translated unless it appears to be necessary to do so.*** The examiner should not require that a translation be filed by applicant. The examiner should not make any comment such as that the non-English language information has only been considered to the extent understood, since this fact is inherent

"Since information is required to be listed in a separate paper rather than in the specification, there is no need to mark "all checked" or "Checked" in the margin of a specification containing citations.

"If a statement fails to comply with the requirements as discussed in this section for an item of information, a line should be drawn through the citation to show that it has not been considered. The other items of information listed that do comply with the rules and this section will be considered by the examiner and will be appropriately initialed.

.....

"A citation listed on form PTO-1449 and considered by the examiner in accordance with this section will be printed on the patent. A citation listed in a separate paper, equivalent to, but not on form PTO-1449, and considered by the examiner in accordance with this section will be printed on the patent if the list is on a separate sheet which is clearly identified as an information disclosure statement and the list lends itself to easy capture of the necessary information by the Office printing contractor, i.e., each item of information is listed on a single line, the lines are at least double-spaced from each other, the information is uniform in format for each listed item, the list includes a column for the examiner's initials to indicate the information was considered. If a citation is not printed on the patent but has been considered by the examiner in accordance with this section, the patent file will reflect that fact...."

Section 3. Statement as to Information Not Found in Patents or Publications (Information Not Listed in Forms PTO/SBI/08A and 08B (formerly PTO-1449))

Section 4. Identification of Prior Application in Which Listed Information was Already Cited and for Which No Copies are Submitted or Need be Submitted.

NOTE: *"A copy of any patent, publication or other information listed in an information disclosure statement is not required to be provided if it was previously cited by or submitted to the Office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 USC 120," 37 CFR 1.98(d)*

WARNING: *"This exception to the requirement for copies of information does not apply to information which was cited in an international application under the Patent Cooperation Treaty." Notice of April 20, 1992 (1138 O.G. 37-41, 38).*

WARNING: *"Information which is cited or submitted to the Office in the parent application of a file wrapper continuing application under 37 CFR 1.62 will be part of the file before the examiner and need not be resubmitted in the continuing application. Likewise, the examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application and thus this information need not be resubmitted unless applicant desires the information to be printed on the patent." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

WARNING: *While a copy of a non-English language item of information need not be submitted, if it was previously submitted to, or cited by, the Office in a prior application, provided it is properly identified in this statement and this application relies on that earlier filing date under 35 USC 120, nevertheless, the requirement of ' 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application. The concise explanation must explain the relevance, as presently understood by the person designated in ' 1.56(c) most knowledgeable about the content of the information. Notice of January 9, 1992, 1135 O.G. 13-25, at 20.*

This application relies, under 35 USC 120, on the earlier filing date of prior application U.S. Serial No. ____,
filed on ____ (date). (Complete the following, if applicable)

This application also relies, under 35 USC 120, on the earlier filing date of prior
application U.S. Serial No. _____, filed on _____ (date).

The following references were submitted to, and/or cited by, the Office in the prior application(s) and,
therefore, are not required to be provided in this application:

Section 5. Cumulative Patents or Publications.

NOTE: *"When the disclosure of two or more patents or publications listed in an information disclosure statement are substantially cumulative, a copy of one of the patents or publications may be submitted without copies of the other patents or publications provided that a statement is made that these other patents or publications are cumulative." 37 CFR 1.98(c).*

NOTE: *"The examiner will then consider only the patent or publication of which a copy is submitted and will so indicate on the list or form PTO-1449 submitted, e.g., by crossing-out the listing of the cumulative information," Notice of April 20, 1992 (1138 O.G. 37-41, 38).*

STATEMENT

_____ is a cumulative of the following patents or publications listed on
Forms PTO/SB/08A and 08B (formerly PTO-1449)

In accordance with 37 CFR 1.98(c) a copy of only _____ is being submitted with this
Information Disclosure Statement.

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: *37 CFR 1.98(a)(2) requires that the Information Disclosure Statement filed under ' 1.97 shall include: A legible copy of (i) each U.S. and foreign patent, (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed, except that no copy of the U.S. patent application need be included...."*

NOTE: *The wording in ' 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (formerly PTO-1449) accompany this information statement.

(complete the following, if applicable)

Exception(s) to above:

.

___ Items in prior application from which an earlier filing date is claimed for this application as identified in Section 4.

___ Cumulative patents or publications identified in Section 5.

Section 7. Concise Explanation of Non-English Language Listed Information Items

NOTE: *"A concise explanation of the relevance, as it is presently understood by the individual designated in ' 1.56(c) most knowledgeable about the content of the information of each patent, publication, or other information listed that is not in the English language shall be included in any information disclosure statement filed under ' 1.97. The concise explanation may be either separate from the specification or incorporated therein." 37 CFR 1.98(a)(3).*

NOTE: *"[T]he explanation required is limited to the relevance as understood by the individual designated in ' 1.56(c) most knowledgeable about the content of the information at the time the information is submitted to the Office." Notice of January 9, 1992, 1135 O.G. 13-25 at 14.*

NOTE: *"Where the information listed is not in the English language, but was cited in a search report by a foreign patent officer, the requirement for a concise explanation of relevance is satisfied by submitted an English language version of the search report." Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

NOTE: *"The concise explanation requirement for non-English language information may be met by submission of an English language version of the search report indicating the degree of relevance found by the foreign office." Notice of January 9, 1992, 1135 O.G. 13-25, at 20.*

WARNING: *"The requirement in ' 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application. Notice of January 9, 1992, 1135 O.G. 13-25 at 20 (emphasis added).*

Section 7A. Concise Explanation of Non-English Language Listed Information Items – EPO Search Report

The relevance with respect to the following citations listed on Forms PTO/SB/08A and 08B (formerly PTO-1449):

is submitted on the basis of the accompanying:

(check the appropriate item)

_____ EPO search report that is in the English language,

_____ EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

Section 7B. Concise Explanation of Non-English Language Listed Information Items – English Language Version of EPO Search Report.

_____ Attached.

Section 8. Translation(s) of Non-English Language Documents

NOTE: *"If a written English language translation of a non-English language document, or portion thereof, is within the possession, custody or control of, or is readily available to any individual designated in '1.56(c), a copy of the translation shall accompany the statement." 37 CFR 1.98(c)*

NOTE: *"The Office does not intend to require translations unless they have been reduced to writing and are actually translations of what is contained in the non-English language information. Applicants should note, however, that most examiners do not have the ability to understand information which is not in English and that the Office will not routinely translate information submitted in a non-English language. The examiner will consider the information insofar as it is understood on its face, e.g., drawings, chemical formulas, English language abstracts, but will not have the information translated unless it appears to be necessary to do so. Applicants are required to aid the examiner by complying with the requirements for a concise examination in 37 CFR 1.98(a)(3) for information submitted in a non-English language." Notice of January 9, 1992, 1135 O.G. 13-25, at 21.*

NOTE: *"The examiner will indicate that the non-English language information has been considered in the same manner as consideration is indicated for information submitted in English." Notice of April 20, 1992 (1138 O.G. 37-41, 41).*

_____ Submitted herewith is an English translation of the following foreign language patents, publications or information or of those portions of those patents, publications or information considered to be material:

(Complete the following, if appropriate)

- ___ No English language translations of the foreign language patents, publications or information or parts thereof are readily available, except for those listed above.
- ___ The following foreign language documents submitted are believed to be the equivalent or substantial equivalent of the English language documents identified below, which are also submitted herewith.

Section 9. Concise Explanation of English Language Listed Information Items (optional)

NOTE: *"Applicants may, if they wish, provide a concise explanation of why English-language information is being submitted and how it is understood to be relevant. Concise explanations are helpful to the Office, particularly where documents are lengthy and complex and applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and applicant is aware that one or more are highly relevant to patentability." Notice of April 20, 1992 (1138 O.G. 37-41, 38)*

Section 10. Identification Of Person(s) Making This INFORMATION DISCLOSURE STATEMENT

The person making this statement is (check each applicable item (a) and (b))

- (a) ___ the inventor(s) who signs below

SIGNATURE OF INVENTOR

Type name of inventor who is signing

- (b) ___ an individual associated with the filing and prosecution of this application (37 CFR 1.56(c))

SIGNATURE OF PERSON

(c) X the attorney who signs below on the basis of the information.

(check each applicable item)

- X supplied by the inventor(s)
— supplied by an individual associated with the filing and prosecution of this application
(37 CFR 1.56(c)).
— in the attorneys file.

Dated: March 17, 2000

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